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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,223	07/11/2003	Eric K. Mangiardi	000100.0015	4411

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EXAMINER

ROGERS, KRISTIN D

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/618,223	Applicant(s) MANGIARDI ET AL.	
	Examiner Kristin D. Rogers	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-24,37 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-24,37 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

1. Applicant's arguments, filed June 15, 2006, with respect to claims 1,3,5-7,10,12,13,37,39,41, and 43 under 35 U.S.C. § 102 (b) have been fully considered and are persuasive. Therefore, this rejection has been withdrawn. Applicant's arguments filed regarding claims 1,3-8,10-24,37 and 39-43 under 35 U.S.C. § 103(a) have been fully considered but they are not persuasive. Applicant argues that Colvin and Jain do not teach arm springs or filaments lying substantially flush against each other from their proximal to distal ends when being retracted within an exterior conduit. The Examiner disagrees. Colvin et al. teaches at least two legs having distal and proximal ends wherein the inward surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed with in the exterior conduit. The Examiner notes that Colvin et al. discloses that the embodiment of Figure 5, although not illustrated, is constructed as such the two legs 54a and 54b will merge into a single cable which fairly suggests the two legs being in flush contact with one another from the distal and proximal ends (column 4, lines 15-20). It is further noted that the embodiment of Figure 1 of Colvin et al. teaches the invention claimed by Applicant. Broadly interpreted, the proximal end of the legs may be considered to be the terminal point at the proximal-most end of each leg and a portion distal to the proximal end of the legs may considered to be a point distal, but immediately adjacent. The distal end of Colvin et al. is considered the region extending the length of element (12 or 52) while the rounded balls (16 or 54a and 54b) are located at the tip. With respect to the embodiment illustrated in Figures 1 and 5 of

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Colvin et al., The Examiner believes that the inward facing surfaces of the legs are continuously in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. See Rejection below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-8, 10-24, 37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain ('147) in view of Colvin et al. ('892).

Jain teaches a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (22); an interior conduit (24) slidably disposed within the exterior conduit and having a depth marking mechanism (42); a measurement assembly (26 or 54) including a plurality of legs (44 or 56, 58) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (24, 30) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open

configuration. The inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed (see Figures 2 and 5). The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit (see Figures 3 and 6). The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length or diameter of the target segment is measured within the patient. Jain teaches all of the limitations of the claims except that the exterior conduit has measurement markers formed on a portion thereof and that the depth markings on the interior conduit are visible through the exterior conduit.

Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal

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end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit. The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a stenotic target segment of the lumen within the patient, including the height and length of the stenosis.

Applicant has not disclosed that using a measurement indicator arrangement having a plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement indicator arrangement of Jain, or applicant's invention, would perform equally well with the plurality of measurement markers formed

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on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit, similar to the arrangement taught by Colvin et al. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Jain to include a measurement indicator arrangement similar to that of Colvin et al, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jain.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is

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571.272.7293. The examiner can normally be reached on Monday through Friday
8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDR

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